

# Notice of Allowability

Application No.

09/700,643

Examiner

Bao-Thuy L. Nguyen

Applicant(s)

MATSUMOTO ET AL.

Art Unit

1641

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed on 6/14/2004 and Interview Summary.
2. ☒ The allowed claim(s) is/are 4, 5, 7, 9-11, 14, 18-21 and 25-31 which have been renumbered from 1-18.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Bao-Thuy L. Nguyen  
Primary Examiner  
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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Chao on August 31, 2004.

The application has been amended as follows:

In the claims:

Claims 1-3 (cancel)

<sup>1</sup>  
Claim ~~4~~ (currently amended) A monoclonal antibody that specifically [[reacting with]] binds to a peptide having an amino acid sequence of residues 12 to 24 of SEQ ID NO: 2.

<sup>2</sup>  
Claim ~~5~~ (previously presented) The monoclonal antibody as claimed in claim ~~4~~ <sup>1</sup> which is a mouse IgG.

Claim 6 (cancel)

<sup>3</sup>  
Claim ~~7~~ (currently amended) A method of [assaying the] detecting 19P2 ligand [or a derivative thereof] in a test fluid which comprises using the monoclonal antibody of claim ~~4~~ <sup>1</sup> in an assay, said assay comprising:

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contacting the ~~[[a]]~~ test fluid sample ~~[[to be assayed]]~~ with said monoclonal antibody, ~~[[and]]~~

detecting ~~[[ligand in said sample]]~~ any complexes form from the binding of said 19P2 ligand with said monoclonal antibody, and

relating the present or amount of said complexes to the present or amount of 19P2 ligand in said sample.

Claim 8 (cancel)

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Claim ~~9~~ (currently amended) ~~[[A]]~~ An isolated hybridoma cell producing the monoclonal antibody of claim ~~4~~<sup>1</sup>.

5

Claim ~~10~~ (previously presented) The monoclonal antibody of claim ~~4~~<sup>1</sup>, which specifically binds with a peptide having the amino acid sequence of SEQ ID NO: 11.

6

Claim ~~11~~ (currently amended) A method for detecting 19P2 ligand in a sample, comprising:

5

contacting said sample with the monoclonal antibody of claim ~~10~~<sup>5</sup>, and

detecting ~~[[such ligand]]~~ any complexes form from the binding of said 19P2 ligand to said monoclonal antibody, and

relating the present or amount of said complexes to the present or amount of 19P2 ligand in said sample.

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Claims 12-13 (cancel)

<sup>13</sup>  
Claim ~~14~~ (currently amended) A method for detecting 19P2 ligand in a sample, comprising:

contacting said sample with <sup>5</sup>[[a]] the monoclonal antibody of claim ~~10~~ and a second antibody comprising an antibody which specifically binds to a peptide having the amino acid sequence of SEQ ID NO: 7, and

detecting [[such ligand]] any complexes form from the binding of the monoclonal antibody of claim <sup>5</sup>~~10~~, said 19P2 ligand and said second antibody, and relating the present or amount of said complexes to the present or amount of 19P2 ligand in said sample.

Claims 15-17 (cancel)

<sup>14</sup>  
Claim ~~18~~ (previously presented) The monoclonal antibody of claim <sup>1</sup>~~4~~, which specifically binds with a peptide having the amino acid sequence of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 5, or SEQ ID NO: 12.

<sup>15</sup>  
Claim ~~19~~ (previously presented) The monoclonal antibody of claim <sup>1</sup>~~4~~, which specifically binds with a peptide having the amino acid sequence of amino acid residues 12 to 24 or SEQ ID NO: 1, amino acid residues 12 to 24 of SEQ ID NO: 2, or amino acid residues 12 to 24 of SEQ ID NO: 3.

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<sup>16</sup>  
Claim ~~20~~ (previously resented) The monoclonal antibody of claim ~~4~~<sup>1</sup>, which specifically binds with a 19P2 ligand peptide, but which does not bind with a peptide having the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 6.

<sup>17</sup>  
Claim ~~21~~ (currently amended) The monoclonal antibody of claim ~~4~~<sup>1</sup>, which is P2L-1Ta, as secreted by hybridoma NIBH 6300.

Claims 22-24 (cancel)

<sup>18</sup>  
Claim ~~25~~ (currently amended) An isolated hybridoma cell line, having accession number NIBH 6300, said cell line producing the antibody P2L-1Ta.

<sup>7</sup>  
Claim ~~26~~ (currently amended) The method of claim ~~11~~<sup>6</sup> further comprising: assaying said sample wherein said 19P2 ligand is attached to a carrier.

<sup>8</sup>  
Claim ~~27~~ (previously presented) The method of claim ~~11~~<sup>6</sup> wherein said monoclonal antibody is attached to a carrier.

<sup>9</sup>  
Claim ~~28~~ (previously presented) The method of claim ~~11~~<sup>6</sup> wherein said monoclonal antibody is attached to a detectable signal or label.

<sup>10</sup>  
Claim ~~29~~ (previously presented) The method of claim ~~11~~<sup>6</sup> which is a sandwich assay.

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<sup>11</sup>  
Claim ~~30~~ (previously presented) The method of claim ~~11~~<sup>6</sup> which is a competitive inhibition assay.

<sup>12</sup>  
Claim ~~31~~ (currently amended) The method of claim ~~11~~<sup>6</sup> in which [[one]] the monoclonal antibody is P2L-1Ta.

### *Reasons for Allowance*

2. The following is an examiner's statement of reasons for allowance: the instant claims define over the prior art of record because the prior art of record fails to disclose a monoclonal antibody that specifically binds to a peptide having an amino acid sequence of residues 12-24 of SEQ ID NO: 2.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


### *Conclusion*

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
8/31/04